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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,315	10/24/2005	Shin-Jen Shiao		2698

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EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
09/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,315	SHIAO, SHIN-JEN	
	Examiner	Art Unit	
	TIMOTHY THOMAS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *64-66,68-74,77,78 and 81-93* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *64-66,68-74,77,78 and 81-93* are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's review of this application reveals that applicant has attempted to prosecute this application on their own as a pro se. While an applicant may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is, therefore, encouraged to secure the services of a registered patent attorney or agent (i.e., registered to practice before the U.S. Patent and Trademark Office) to prosecute the application, since the value of a patent is largely dependent upon skillful preparation and prosecution.

The Office cannot aid you in selecting a registered attorney or agent, however, a list of attorneys and agents registered to practice before the U.S. Patent and Trademark Office is available from the USPTO web site, http://www.uspto.gov. For assistance locating this information, contact the Office of Enrollment and Discipline at (571) 272-4097 or call the Inventors Assistance Center toll-free number, 1(800)786-9199.

Previous Election Made

2. Applicant's election with traverse of Group I in the reply filed on 8/8/2011 is acknowledged. The traversal is on the ground(s) that 1) quoting from UKIPO 2008 Guidelines for Examination that there is no need to show proof of application to every individual possible instance which could fall within the scope of the claim; with a discussion of protons being supplied by administering an edible acid, which inhibits

histamine, the main factor of hypersensitivity diseases; that all of the acids used have the same property of releasing the same protons, lowering the humoral pH and showing the same results of inhibiting histamine; that there is no way to elect any more; the applicant request assessing the support for the invention by a new concept, but not by the traditional concept of one compound only for one kind of ailment, because the way of disease treatment is completely different from the traditional methods. 2) Ohashi is not concerning the invention, because the abstract identifies phosphoric acid as a stabilizing agent for AS-3201, and do not concern treatment of ailment at all. This is not found persuasive because UKIPO documents do not determine the laws and rules for US practice; applicant should identify US law or MPEP sections, which control US patent prosecution when making future arguments. Claim 64, for example, is drawn to a pharmaceutical composition comprising, in one embodiment, phosphoric acid (edible acid) and/or its acidic salts of sodium or potassium and a pharmaceutically acceptable carrier, which contains a range of the recited amount of edible acid. The claims do not require any method step (based on the election of a product); in other words, in a claimed product, any intended use of said product is not given patentable weight.

In response to applicant's argument that all of the acids used have the same property of releasing the same protons, lowering the humoral pH and showing the same results of inhibiting histamine, the main factor of hypersensitivity diseases, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Ohashi contains phosphoric acid in an amount required by the instant claims, anticipating claim 64. It is immaterial that Ohashi teaches a different purpose for this product. The claims require the technical feature of the structure of a pharmaceutical composition containing 0.06-100 wt% edible acid, which includes phosphoric acid (as one alternative edible embodiment in amended claim 64) and a carrier. The components are taught by Ohashi, which anticipates the technical feature linking the Groups. This establishes that unity of invention is lacking among the claims presented for examination.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that applicant did not formally elect Group I, but canceled claims drawn to Groups II and III. This is taken as the election of Group I.

3. It is noted that the reply filed 8/8/2011 is formally non-compliant because the response fails to elect each component in a single disclosed pharmaceutical composition, according to (i); and by failing to elect one of (ii-a) or (ii-b) or (ii-c) or (ii-d) or (ii-e) (See requirement at Item 3 in the 7/12/2011 Restriction Requirement). However, in view of the cancelation of claims 67, the modification of the recited edible acids to claim 64, the similar subject matter in claims 64, 74 and 78, and the addition of new claims 85-93, alternate species are required. The Species Election Requirement of Item 3, mailed 7/12/2011 is withdrawn, and is replaced with the following species election requirement.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant must elect a single specie for each of (i), (ii) & (iii):

(i) a single edible acid (claims 64, 74, 78); elect one of (i-a)-(i-m):

(i-a) phosphoric acid;

(i-b) fumaric acid;

(i-c) maleic acid;

(i-d) malic acid;

(i-e) tartaric acid;

(i-f) citric acid;

(i-g) lactic acid;

(i-h) α-hydroxy oxtanoic acid;

(i-i) gluconolactone;

(i-j) α-hydroxy ethanoic acid;

(i-k) acetic acid;

(i-l) propionic acid; or

(i-m) succinic acid.

(ii) a single form specie; elect one of (ii-a) – (ii-e):

(ii-a) oral form (claim 66); if elected, applicant must also elect a single form specie from the species recited in claim 66 (e.g., a tablet);

(ii-b) injection (claim 68);

(ii-c) a health care food (claim 70); if elected, elect a single food form specie from the species recited in claim 71 (e.g., a tea);

(ii-d) topical form (claim 65);

(ii-e) non-oral form (claim (65); if elected, elect a non-oral agent specie from the species recited in claim 69 (e.g., a paste), or for cloth or for grove (claim 77) or topical adhesive agent (claim 90) or hair lotion (claim 92) or water bath (claim 92);

(iii) a single ailment (as the intended use of the recited pharmaceutical composition) specie; elect one of (iii-a) – (iii-e):

(iii-a) colds (claim 85);

(iii-b) insect bit[e] (claim 86);

(iii-c) inflammation (claim 87);

(iii-d) itch (claim 88);

(iii-e) free radical scavenger (claim 89);

(iii-f) depression of enzyme activity (claim 91);

(iii-g) pustules (claim 93).

Applicant is required, in reply to this action, to elect 1) a single edible acid species under (i); **and** 2) a single form under (ii); **and** 3) a single ailment under (iii), to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. **An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election**.

It is noted that the above species election requirement could be satisfied by the following three elections (given as an example), which would satisfy the species election requirement outlined above:

(i-a) phosphoric acid as the edible acid under (i);

(ii-c) a health care food as the single form under (ii), with the additional elected single food specie of a sarsaparilla, from claim 71; and

(iii-b) insect bite, as the single ailment under (iii).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: all claims are generic for (i); claims 65 and 69 are generic for (ii); claims 64-66, 68-74, 77-78, 81-84, 90 and 92 are generic for (iii).

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical

features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

5. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the species is a composition containing 0.06-100 wt % of an edible acid (or a salt thereof) and a carrier. As discussed in the record, and above, Ohashi et al. (US 6,297,244 B1; 2001; previously cited) teaches pharmaceutical compositions containing phosphoric acid (a recited edible acid; abstract), the acid content being present in the range of about 0.2-about 10% (within the instant recited concentration range; col. 2, lines 19-23); the pharmaceutical compositions include carriers (col. 2, lines 28, 33). Since Ohashi previously disclosed the technical feature, the technical feature lacks novelty.

Therefore, the technical feature linking the species does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly the species are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Primary Examiner, Art Unit 1628